

**IMMEDIATE RELEASE**

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**DoD to Resume Anthrax Vaccinations**

The Department of Defense announced today a resumption of the mandatory Anthrax Vaccine Immunization Program (AVIP) for military personnel, emergency-essential DoD civilians and contractors, based on defined geographic areas or roles.

For the most part, mandatory vaccinations are limited to military units designated for homeland bioterrorism defense and to U.S. forces assigned to the U.S. Central Command area of responsibility and Korea.

The under secretary of defense for personnel and readiness will issue implementing instructions to the military services for resuming the mandatory vaccination program within 30 to 60 days.

"The anthrax vaccine will protect our troops from another threat--a disease that will kill, caused by a bacteria that already has been used as a weapon in America, and that terrorists openly discuss," said Dr. William Winkenwerder Jr., assistant secretary of defense for health affairs.

The policy also allows personnel previously immunized against anthrax, who are no longer deployed to higher threat areas, to receive follow-up vaccine doses and booster shots on a voluntary basis

Under the voluntary vaccination policy, implemented during the period of a court injunction throughout 2005, the voluntary acceptance rate was about 50 percent.

"This rate of vaccination not only put the service members at risk, but also jeopardized unit effectiveness and degraded medical readiness. The threat environment and the unpredictable nature of terrorism make it necessary to include biological warfare defense as part of our force protection measures," Winkenwerder said.

Anthrax is a deadly infection, and the anthrax vaccine is an important force protection measure to combat it. In the fall of 2001, 22 cases of anthrax resulted from attacks with anthrax spores through the U.S. postal system. Five people died in these attacks.

The Food and Drug Administration has repeatedly found, and independent medical experts have confirmed, that anthrax vaccine is safe and effective.

For more information on the anthrax vaccination program visit <http://www.vaccines.mil/> or <http://www.vaccines.mil/anthrax> .

SECDEF WASHINGTON DC//PA-PO//

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SUBJECT: Public Affairs Guidance (PAG) - Anthrax Vaccine Immunization Program (AVIP) Resumption of Mandatory Vaccinations for Selected Military

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SUBJECT: PUBLIC AFFAIRS GUIDANCE (PAG) - ANTHRAX VACCINE IMMUNIZATION PROGRAM (AVIP) MANDATORY VACCINATIONS FOR SELECTED MILITARY

REF: A. SECDEF MSG, DTG 282100Z Jun 02, Public Affairs Guidance - resumption of Anthrax Vaccine Immunization Program (AVIP); B. SECDEF MSG, DTG 282130Z Jun 02, Public Affairs Guidance (continued) - resumption of Anthrax Vaccine Immunization Program (AVIP); C. SECDEF MSG, DTG 241956Z Dec 03, Public Affairs Guidance (PAG) - Anthrax Vaccine Immunization Program (AVIP) Judicial Decision

POC/MICHAEL T. HALBIG/LT COL, USAF/OASD(PA) PRESS OFFICE/TEL:703-695-2528//

1. This message supplements Ref's A and B and supercedes Ref. C.
2. Public Affairs posture for all aspects of the AVIP is active. Public Affairs Officers are authorized and encouraged to widely distribute information contained herein to both internal and external audiences.
3. OASD(PA) released the following statement on 7 Jan 04: (QUOTE) Under Secretary of Defense for Personnel and Readiness David S. C. Chu signed a memo today resuming the Anthrax Vaccine Immunization Program. A copy of the memo can be seen at <http://www.defenselink.mil/news/Jan2004/d20030107anthrax.pdf>. (END QUOTE)
4. TALKING POINTS:
  - 4.a. The Department took steps January 7, 2004, to resume giving anthrax vaccinations.
  - 4.b. The health and safety of our men and women are our top concerns. Immunizations are but one aspect of ensuring the health and safety of our people.
  - 4.c. Anthrax is deadly. The threat for certain forces is real. Vaccination offers a layer of protection, in addition to antibiotics, needed for certain members of the armed forces.
  - 4.d. The anthrax vaccine that DoD uses is safe and effective and has been licensed by the FDA since 1970 without interruption.

4.e. On December 30, 2003, the FDA reaffirmed in a "Final Rule and Order" that was published in the Federal Register January 5, 2004, that the anthrax vaccine is safe and effective for the prevention of anthrax disease, regardless of the route of exposure.

4.f. It has been and continues to be clear DoD policy to comply with all FDA and other legal requirements in its use of the anthrax vaccine.

## 5. Questions and Answers:

Q1. What is DoD's current anthrax vaccination policy?

A1. As of January 7, 2004, anthrax vaccinations in the Department of Defense have resumed, at the direction of the Under Secretary of Defense for Personnel & Readiness, Dr. David Chu. The program resumed after the U.S. District Court for the District of Columbia issued a stay of an injunction against the anthrax vaccination program issued December 22, 2003. This court action lifts the injunction and permits troops once again to be protected against the lethal bioweapon anthrax. Anthrax vaccinations on hold since December 23, 2003 now resume. Troops will be vaccinated where they left off. No one will restart the vaccination series from the beginning. Throughout this process, the Anthrax Vaccine Immunization Program (AVIP) was never cancelled.

Q2. How did the injunction get lifted?

A2. The Department of Justice filed a motion with the U.S. District Court for the District of Columbia, requesting a stay. On January 7, 2004, the judge granted the motion for a stay, thus allowing for resumption of the DoD Anthrax Vaccine Immunization Program (AVIP), except that the injunction is still in place for the six "John Doe" individuals who initiated the litigation. The identities of these individuals is unknown to the Department of Defense.

Q3. Where did the injunction come from?

A3. On December 22, 2003, the United States District Court for the District of Columbia issued a preliminary injunction against the current operation of the AVIP. Safety of the vaccine was not the focus of the injunction. The judge ruled based his conclusion that the Food and Drug Administration (FDA) had not formally determined that the vaccine was approved for use against inhalational anthrax.

Q4. What is FDA's position about the effectiveness of anthrax vaccine?

A4. For years, FDA has held that anthrax vaccine prevents anthrax, regardless of the route of exposure. On December 30, 2003, the FDA reaffirmed this position in a "Final Rule and Order" that was published in the Federal Register on January 5, 2004. The FDA press release appears at: [www.fda.gov/bbs/topics/NEWS/2003/NEW01001.html](http://www.fda.gov/bbs/topics/NEWS/2003/NEW01001.html). The full text of the FDA final rule appears at [www.access.gpo.gov/su\\_docs/fedreg/a040105c.html](http://www.access.gpo.gov/su_docs/fedreg/a040105c.html).

Q5. Why is resuming anthrax vaccinations so important?

A5. Anthrax vaccinations provide the best protection against a lethal weapon. DoD is committed to protecting American troops and knows that anthrax vaccinations are the best round-the-clock measure to protect our troops.

Q6. Why didn't you allow personnel to choose voluntarily to be vaccinated against anthrax?

A6. The implications of the judge's order precluded anthrax vaccinations except under the extremely detailed and time-consuming requirements of the FDA's "investigational new drug" provisions. DoD does not consider anthrax vaccine an investigational drug to protect the troops. Because of this, voluntary anthrax vaccinations under the terms of the injunction could not be provided.

Q7. What about all those people who received anthrax vaccinations in the past? Do they have to start the six-dose series from the beginning?

A7. No. Prior doses count. People resume the vaccination program where they left off.

Q8. What happens to people whose regularly scheduled dose was delayed?

A8. Those individuals do not start the series over again, they resume the series from the point where they left off. There is no reason for concern that interrupting the anthrax vaccination series causes any harm. Each dose of anthrax vaccine is like walking up a set a stairs. You may remain on one step longer than originally planned, but the next dose of vaccine will resume development of protective immunity (climbing further up the stair case).

Q9. How many service members have been vaccinated?

A9. DoD has vaccinated more than 1 million service members since the beginning of the AVIP program in March 1998, using more than 3.7 million doses of anthrax vaccine. Since June 2002, we have immunized more than 625,000 service members with more than 1.6 million doses of anthrax vaccine.

Q10. Does DoD experiment on service members or use them as "guinea pigs"?

A10. Absolutely not. The purpose of military vaccination programs is to keep our troops healthy and help them return home safe.

Q11. How common are refusals of anthrax vaccination?

A11. Since inhalational anthrax in fall 2001 killed five people in the United States, very few people in DoD have refused anthrax vaccination. About ten people have been separated from military service related to refusing to participate in the vaccination program between 2001 and 2003.

Q12. How will anthrax-vaccine refusals be handled now that the injunction is lifted?

A12. There will be no change from the methods employed before the injunction was put in place. DoD begins by assuming that someone refusing the vaccine is not aware of the science that provides the foundation for the vaccine's safety and effectiveness. So, our first action is to determine their concern and provide information about the deadly effects of anthrax spores and the protection afforded by the vaccine. Someone refusing vaccination is reeducated by a healthcare professional, counseled about the career implications of refusing a lawful order, provided multiple opportunities to ask questions, and provided legal counsel.

We anticipate that very few service members will refuse to be vaccinated, given the clearly lethal effects of anthrax spores and the FDA's clear statements about the safety and effectiveness of vaccination.

This is a force protection issue. If a service member continues to refuse the vaccine, then a commander will manage the situation as he or she would for any failure to obey a lawful order. Legal adjudications consistently have found orders for members to be vaccinated to be lawful orders.

Q13. What is the threat of anthrax used against our military?

A13. Anthrax is an attractive weapon of mass destruction for our enemies. It is highly lethal, relatively easy to produce in large quantities and to develop as a weapon, easily spread in the air over a large area and it can be stored and remain dangerous for a long time. For this reason, anthrax may be the most important biological warfare threat facing U.S. forces. The intelligence community believes several countries currently have or are developing an offensive biological warfare capability using anthrax. Given the ease with which anthrax can be produced, U.S. forces may have little or no warning before an anthrax attack, which could be delivered by unconventional means.

Q14. How did DoD ensure people were protected against weaponized anthrax during the interruption in vaccinations?

A14. DoD is concerned about the health and safety of all service members, including those assigned or deployed in high threat areas. That is why we paid careful attention to other pillars of Force Protection, including protective masks and suits, detection equipment, ongoing surveillance and intelligence gathering and stockpiling antibiotics in the event of exposure.

Q15. Why doesn't DoD use antibiotics rather than anthrax vaccine?

A15. There is no better round-the-clock protection against anthrax infection than the anthrax vaccine. Antibiotics are effective when started immediately or very soon after exposure. However, not all exposures can be predicted in advance or even recognized in very early stages, particularly in certain military situations. Antibiotics cannot be used for long periods of time before a biological attack, because antibiotics have a known set of adverse reactions.

Q16. Does anthrax vaccine protect people against inhalational anthrax?

A16. Yes. The DoD shares the repeated findings of the FDA, the National Academy of Sciences, and numerous other authoritative experts that anthrax vaccine is effective against anthrax, regardless of the means of exposure.. In a report commissioned by the United States Congress, the National Academy of Sciences' Institute of Medicine concluded in March 2002 that anthrax vaccine is "an effective vaccine for the protection of humans against anthrax, including inhalational anthrax, caused by all known or plausible engineered strains of *Bacillus anthracis*."

Q17. Is anthrax vaccine safe?

A17. Yes. The DoD shares the repeated findings of the FDA, the National Academy of Sciences, and numerous other authoritative experts that anthrax vaccine is safe.

6. OASD (PA) POC is Jim Turner, (703) 697-5135, DSN 227-5135, email [james.turner@osd.mil](mailto:james.turner@osd.mil). The toll-free number for additional information regarding the AVIP IS 1-877-GET-VACC (1-877-438-8222) or the AVIP website at <http://www.anthrax.mil>.

## **DoD to Resume Mandatory Anthrax Vaccinations for Select Groups, Talking Points (18 Oct 06)**

**Q: Why change the policy now? Has there been an elevation in the threat?**

A: We vaccinate our service members to protect them against deadly diseases – both natural and those potentially spread by terrorists or enemy forces. Under the voluntary policy, only about 50% of our service members in high threat areas who were contacted about vaccination volunteered to be vaccinated. This low rate of vaccination not only put the service members at risk, but also jeopardized unit effectiveness and degraded medical readiness.

**Q: Why do you think the voluntary acceptance rate for anthrax vaccine has been so low? Does it tell you that military members do not believe you that this is a safe vaccine?**

A: No. A 50% acceptance rate is about what we expected, based on voluntary vaccination programs in the general public. Nobody likes getting shots. I think the biggest reason for the difference we have had between a 99.9% acceptance rate for mandatory anthrax shots and a 50% rate for voluntary shots is because military members expect that if something is important to the mission, it will be mandatory. Protection against anthrax is important to the mission, and that's why we are returning to a mandatory program for those at higher risk.

**Q: How do we know that the anthrax vaccine is safe and effective?**

A: On 19 December 2005, The Food and Drug Administration (FDA) issued its Final Rule and Final Order stating that anthrax vaccine adsorbed (AVA) is effective in preventing anthrax disease regardless of route of exposure. The licensed vaccine is safe and effective - based on sound science – as determined by eight separate independent reviews including the National Academy of Sciences' Institute of Medicine. The IOM states the adverse events after anthrax immunization are "comparable to those observed with other vaccines administered to adults".

**Q: Won't this policy have a positive/negative impact on Emergent BioSolutions' IPO offering?** [Note: BioPort is now under the company title of Emergent BioSolutions. The company announced on 15 Aug 06 that it has filed a registration statement with the U.S. Securities and Exchange Commission related to the proposed initial public offering of its common stock.]

A: I have no idea what the impact will be on the company. We do not make policy decisions based upon a company's internal business decisions.

**Q: What groups of people are included in the mandatory policy?**

A: Basically, all uniformed personnel and emergency-essential and equivalent DoD civilian employees assigned for 15 or more consecutive days to the U.S. Central Command or U.S. Forces Korea areas of responsibility. There are also provisions for forces afloat, uniformed personnel assigned to special units with biowarfare- or bioterrorism-related missions, and other specially designated units covered by the policy.

**Q: Why is there a voluntary option for those who have received a previous shot but are no longer in a high threat area?**

A: This is good medical practice – allowing our beneficiaries to follow the FDA approved dose schedule. Many of our service members want to be protected – even when they leave the high threat areas. This allows them to continue the vaccinations, become fully protected and provides the US Armed Forces with a more medically ready force.

**Q: What happens if someone refuses to receive the mandatory vaccination? Aren't you concerned that this will decrease morale?**

A: This becomes a commander's decision regarding failure to obey a lawful order. Historically, there have been very few such cases. Most service members follow orders and understand that the vaccinations protect them and their units against a biological attack.

**Q: Given that Judge Sullivan said the mandatory anthrax vaccination program was illegal, is DoD going to correct the military records of individuals who were punished for refusing to obey unlawful orders?**

A. DoD continues to believe the Anthrax Vaccine Immunization Program has been administered consistent with the law, and orders to military personnel to be vaccinated were lawful. No judicial judgment has declared such orders to have been unlawful. Military members who seek a correction of military records may apply to the Board for Correction of Military or Naval Records of the appropriate Military Department